EXHIBIT 3

February 15, 2019

Scott Provencher
Mitchell, Williams, Selig, Gates, & Woodyard, P.L.L.C.
425 W. Capitol Ave, Ste 1800
Little Rock, AR 72201

Re: Defense Expert Anesthesiologist Opinion: Ada Trombley vs. 3M Company

Introduction

Ada Trombley developed a periprosthetic joint infection following otherwise uneventful right total knee replacement surgery in December 2011. Ms. Trombley alleges that the infection was the direct result of a Bair Hugger forced air warming device used during this surgery. As an anesthesiologist and a professional in quality improvement, I have been invited to provide my expert opinions regarding these allegations.

Professional Qualifications

I attended college at Harvard University and Medical School at Tufts. I completed my residency in anesthesiology at the Massachusetts General Hospital in 1991. I served as an Attending Anesthesiologist at the National Naval Medical Center, Bethesda, from 1991-1994 while on active duty in the US Navy. From 1994-2010, I was an Attending Anesthesiologist at the R Adams Cowley Shock Trauma Center and Professor of Anesthesiology at the University of Maryland. During that time, I served for 15 years as the Physician Director of Quality Management and for 5 years as the Center's Director of Clinical Operations.

In 2009, I became the founding Executive Director of the Anesthesia Quality Institute, an organization of the American Society of Anesthesiologists dedicated to the improvement of anesthesia patient care nationwide. While at AQI, I directed the creation and first 6 years of operation of the National Anesthesia Clinical Outcomes Registry, the largest source of anesthesia case data in the country. I also administered the Anesthesia Closed Claim Project and developed and administered the nationwide Anesthesia Incident Reporting System. In 2015, I became the first Chief Quality Officer of US Anesthesia Partners, now the largest anesthesia private practice in the country. Over the course of my career, I have performed quality reviews of thousands of anesthesia adverse events and published extensively on how to measure and improve the quality of anesthesia care. I practice clinically at Baylor University Medical Center in Dallas.

I am familiar with the Bair Hugger patient warming system. I have used it to preserve normothermia in thousands of orthopedic surgery patients in the past 20 years.

Materials Reviewed and/or Considered

I have reviewed and/or considered the following materials related to this case:

- Medical records, including operating room and anesthesia records, Bay Park Community Hospital, December 2011
- Nicolasora, Nelson, M.D. – Infectious Disease Assoc of NW Ohio (TROMBLEYAL-10JVA-000149 -216)
- ProMedica Physicians -Beer Orthopaedics (TROMBLEYAL-13PPBO-00001-00057)
- ProMedica Wildwood Orthopedic and Spine Hospital (TROMBLEYAL-45PWOSH-00005-00012)
- ProMedica Toledo Hospital (TROMBLEYAL-47PTH-00089-00216)
- ProMedica Toledo Hospital (TROMBLEYAL-48PWOSH-00013-00429)
- ProMedica Laboratories (TROMBLEYAL-49PML-00001-00032)
- Fact witness depositions: Trombley, Ada; Trombley, Fred; CRNA Lauren Peterson; Drs. Bradley Everly, Karl Beer, Nelson Nicolasora, Tammen Abdul-Aziz
- Expert testimony of Dr. Elghobashi (in the Gareis trial);
- Expert report of Dr. William Jarvis, in both the Trombley case and his general causation report
- Expert report of Dr. Eric Brown
- Supplemental Expert report of Dr. Yadin David
- Expert report of Dr. Nathan Bushnell
- Aalirezaie et al. Proceedings of International Consensus Meeting on Orthopedic Infections: General Assembly, Prevention, Operating Room Environment. J Arthroplasty 2018.
- ICM General Assembly Questions and Answers
- Barrier Easy Warm press release
- Tjoakarfa, et al. Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Patient Normothermia During Hip and Knee Arthroplasty Surgery. J Arthroplasty 2017
- Kanmed WarmCloud User Manual
- Kanmed WarmCloud Brochure
- Reyntjens, et al. Perioperative temperature management. Comparison of a forced air warming device and a dynamic air mattress device in plastic surgery. Eur J Anaesthesiology 2008
- Inditherm patient warming mattress for the prevention of inadvertent hypothermia. NICE Clinical Guideline 2011
- LMA PerfecTemp PowerPoint
- Egan, et al. A Randomized Comparison of Intraoperative PerfecTemp and Forced-Air Warming During Open Abdominal Surgery. Anesth Analg 2011;113:1076–81
- Raeder, et al. Reduced hypothermia and improved patient thermal comfort by perioperative use of a disposable active self-warming blanket. Poster presentation.
- Kurz et al. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. N Engl J Med 1996
- Melling et al. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. Lancet 2001

- Sandoval et al. Safety and efficacy of resistive polymer versus forced air warming in total joint surgery. Patient Safety in Surgery 2017
- Scott et al. Compliance with Surgical Care Improvement Project for body temperature management (SCIP Inf-10) is associated with improved clinical outcomes. Anesthesiology 2015
- Sun et al. Intraoperative core temperature patterns, transfusion requirement and hospital duration in patients warmed with forced air. Anesthesiology 2015
- Frisch et al. Intraoperative Hypothermia in Total Hip and Knee Arthroplasty. Orthopedics 2017
- Avidan et al. Convection warmers – not just hot air. Anaesthesia 1997
- Moretti et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? J Hospital Infection 2009
- McGovern, et al. Forced-air warming and ultra-clean ventilation do not mix J. Bone and Joint Surg 2011
- Wang et al. Incidence and predictors of surgical site infection after ORIF in calcaneus fractures, a retrospective cohort study. J Orthop Surg Res. 2018
- Crews, et al. Risk Factors for Surgical Site Infections Following Vertical Expandable Prosthetic Titanium Rib (VEPTR) Surgery in Children. Spine Deform. 2018
- Zhang, et al. The effects of a forced-air warming system plus electric blanket for elderly patients undergoing transurethral resection of the prostate: A randomized controlled trial. Medicine (Baltimore) 2018
- Albrecht et al. Forced air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011
- Albrecht et al. Forced-air warming: a source of airborne contamination in the operating room? Orthopedic Reviews 2009
- Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone Joint Surg 2012
- Legg and Hamer. Forced-air patient warming blankets disrupt unidirectional airflow. Bone Joint J 2013
- Stocks et al. Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery. Am J Inf Control 2010
- August 30, 2017 FDA letter to healthcare professionals

Relevant Facts of the Case

Ms. Ada Trombley was a 62-year old woman when she presented for right total knee replacement at Bay Park Community Hospital in December 2011. Notable comorbidities were obesity, non-insulin dependent diabetes, hypertension and arthritis. Chronic medications included a statin, glipizide, Coreg and 10 mg of prednisone per day. A recent echocardiogram showed an ejection fraction of 67%. Anesthesia pre-op evaluation rated her ASA Physical Status 3 based on the serious comorbidities noted. The patient received a spinal anesthetic outside the operating room (OR) and was then brought into the room and positioned for surgery. Intraoperatively she received midazolam and a propofol infusion for sedation. A Bair Hugger blanket was used to maintain normothermia.

The operation proceeded uneventfully, with a surgical time of 71 minutes. Antibiotic prophylaxis was noted as Cefazolin 2 grams, given 21 minutes before skin incision. Temperature ranged from 36-37 degrees C, likely measured via a skin sensor (meaning that core temperature was somewhat higher). The surgical tourniquet was ineffective, and it was removed. The operation was completed with continued blood flow to the leg. Estimated blood loss was 400 mL; fluids were 1700 mL of lactated ringer's solution and urine output was 200 mL. In-room time was 127 minutes. Postoperative anesthesia quality capture noted no adverse or unusual events. Her temperature on arrival to the recovery room was 36.4 degrees C, a normal body temperature. There is no notation in the recovery room record of Ms. Trombley shivering post-operatively or experiencing adverse cardiac events. Recovery from anesthesia was unremarkable.

Mrs. Trombley received 2 more doses of Cefazolin postoperatively. She was discharged on postoperative day (POD) 2 in good condition, with no concerns noted with the surgical wound. This was also true at her postoperative visit with her orthopedic surgeon on POD 13, at which time the wound was noted to be healing well. However, four weeks later Ms. Trombley returned with fever and chills and signs consistent with deep wound infection. She was returned to the OR on January 11 and underwent reopening of the surgical wound, multiple cultures, removal of all hardware, debridement and irrigation of the knee and placement of antibiotic cement spacers. Multiple cultures grew Group B Strep, which was treated with antibiotics. Her recovery was complicated by renal failure, but she eventually recovered sufficiently to have new knee hardware placed on August 31, 2012.

Expert Opinions and Basis

All of my expert opinions contained in this report are based on a reasonable degree of medical probability. They are based on my education, training, experience, review of scientific and medical literature, and my review of the medical records and materials in this case.

1. Based on extensive experience reviewing anesthesia records, and my education, training and many years of experience as an anesthesiologist providing anesthesia services and treatment to patients undergoing orthopedic procedures, it is my expert opinion that Ms. Trombley received an excellent anesthetic, well within the standard of care. The doses of medications administered and the anesthesia techniques used were consistent with the normal and standard practice of anesthesiology for total knee replacement. It is also my expert opinion that the anesthesia team acted appropriately in using the Bair Hugger warming device to maintain Ms. Trombley's normal body temperature throughout the procedure. The Bair Hugger helped achieve many benefits, further explained below, to Ms. Trombley that come from maintaining normal body temperature.

   The importance of warming patients intraoperatively during total knee surgeries, including warming Ms. Trombley during her surgery in December 2011, cannot be overstated. The most important reference is Kurz et al (1996) which noted the increased incidence of postoperative wound infection associated with patients who arrive in the PACU hypothermic. While Kurz' observation was originally made in patients undergoing colorectal surgery, the findings have since been confirmed in multiple studies in multiple types of surgery, including

orthopedic surgery (Wang et al., Crews et al.). Further studies (Scott et al, Frisch et al, Zhang et al) have also demonstrated reduced need for blood transfusion, reduced occurrence of shivering in the PACU and increased patient satisfaction in normal versus hypothermic patients. In a higher-risk patient like Ms. Trombley, postoperative shivering puts stress on the heart and circulatory system and creates a concern for myocardial ischemia. In my opinion, keeping Ms. Trombley warm was an essential intervention to reduce multiple potential risks during this surgical procedure. It is also my expert opinion that the use of the Bair Hugger during Ms. Trombley's surgery kept her temperature within a normal range, reduced her risk of shivering post-operatively and reduced her risk for needing a blood transfusion. Ms. Trombley did not have adverse cardiac events documented in her anesthesia or recovery room record. All these findings demonstrate that the Bair Hugger was safe and effective for Ms. Trombley during her December 2011 surgery.

My opinion on intraoperative warming as an essential intervention for Ms. Trombley during a major surgery is consistent with and has been validated by the Centers for Medicare and Medicaid Services (CMS), who have included a maintenance-of-temperature measure as a required element of performance reporting for anesthesiologists.

2. The Bair Hugger forced air warming system is the preferred choice for maintaining normothermia in the majority of major surgical cases performed in the United States, including the majority of knee replacement surgeries. The Bair Hugger blanket, placed on top of the patient is easier to put on and off and interferes less with patient positioning than underbody warming systems, making the Bair Hugger blanket more likely to be used, and more likely to be kept in contact with the patient for longer periods. In specific refutation of a statement by Dr. Jarvis, it should be noted that bacterial contamination is not found in the air delivered by an appropriately used Bair Hugger blanket (see Avidan, 1997).

3. I also note that the Bair Hugger upper body blanket, appropriately applied to Ms. Trombley as described by CRNA Peterson, was several feet from the sterile surgical field and was both adhesively stuck to her skin at her chest and then tucked around her arms and head. This is an important point of normal technique. Mr. Peterson's actions kept the air flowing from the Bair Hugger blanket confined around Ms. Trombley's skin at her upper body and chest where it effectively warmed her. Several layers of surgical drapes then covered the blanket and further separated it from the sterile field at Ms. Trombley's knee.

4. The majority of electrical devices in the OR have cooling fans which produce local disturbances in air flow, and for this reason they are kept further from the patient. The 6-foot hose which connects to the Bair Hugger blanket on the patient allows for the unit itself to be positioned 8-10 feet from the sterile field, and well beyond the sterile barrier of the surgical drapes.

5. Ms. Trombley had numerous risk factors for the development of an infection following joint replacement, including her obesity, diabetes, hypertension and chronic use of steroids. Recognizing this, her anesthesia team took actions to mitigate this risk. These included administration of prophylactic antibiotics and keeping her warm throughout the surgical procedure. Mr. Peterson, CRNA, described the appropriate use of the Bair Hugger to keep

Ms. Trombley warm. He applied the Bair Hugger blanket before the leg was cleaned and prepped for surgery and affixed the blanket to the skin at her chest and then tucked it around her arms and head to keep the air generated by the blanket in contact with her skin and upper body, and far away from the surgical field. The surgical drapes were then affixed tightly around the leg and layered over the Bair Hugger blanket on Ms. Trombley's chest, and the drapes were raised on poles isolating the sterile surgical field away from the non-sterile area where anesthesia personnel worked.

6. Despite these interventions, Ms. Trombley developed a surgical site infection (SSI) six weeks after the operation. Given the later onset of the infection and the early healing of the surgical wound – as documented by Dr. Beer two weeks after the operation -- it is more likely that the wound became contaminated after the time of surgery. Group B Strep is a known endemic bacteria in the human gut and genitourinary system and can contaminate the skin in multiple ways. It is not a bacteria normally found on skin which has been cleaned for surgery or on OR surfaces, such as the floor, which are regularly cleaned. Dr. Jarvis has not explained how Group B strep, a bacteria normally in the gut and genitourinary system, was in the air in the operating room at the time of Ms. Trombley's surgery.

7. Normal immune system function of the skin and subcutaneous tissue keeps the majority of patients from developing infections. Ms. Trombley's decreased tissue perfusion due to hypertension, obesity and diabetes created a more favorable environment for an infection to form. Ms. Trombley's chronic use of steroids additionally depressed her immune system, making it harder for her to fight off developing infections. I disagree with Dr. Jarvis that Ms. Trombley's chronic steroid use would not be immunosuppressive.

8. It is more likely that at some time after the surgery, and after the time that Ms. Trombley was receiving prophylactic antibiotics, the healing tissue was contaminated with Group B Strep from the gut or vagina and an infection developed. The assertion by Dr. Jarvis that an absence of GI or urinary tract issues at the time of surgery means that her own bacterial flora can be ruled out as a source for the infection is untrue, and I disagree with his opinion. For one, there is nothing in the medical record showing any culture testing of Ms. Trombley's reproductive system (vaginal area) preoperatively to say whether she had an active infection. Further, chronic colonization of the gut and vagina with Group B strep is common in women with no signs of active infection, and this reservoir of bacteria can easily cross-contaminate healing tissue by spread through skin contact or the blood stream. I further disagree with Dr. Jarvis' reliance on a later urinary culture which did not grow Group B strep because at that time the patient had received numerous doses of antibiotics specifically intended to treat this bacteria. Consequently, I disagree with Dr. Jarvis that Ms. Trombley's flora can be ruled out as possible sources of the bacteria that started her infection.

9. As noted above, there is no question that keeping Ms. Trombley warm during her surgery reduced her risk for infection. However, a competitor of the Bair Hugger device raised the question of whether it specifically contributes to SSIs through changes in air flow in the OR. As an expert in anesthesia quality, I have watched the scientific literature on this topic closely over the past decade, and I have reviewed it again as part of this report.

10. As Dr. Jarvis notes in his report, there are numerous disturbances to air flow in a working OR. Most important of these are the surgeons, nurses and technicians moving about during the operation. Because of this ongoing movement of surgeons and personnel, recommended OR design therefore calls for forced air flow through the room from ceiling to floor, with multiple 'turnovers' of air within the room each hour, and I have seen no evidence that the OR in question was defective in this regard. This forced air flow, however, does not stop the ongoing movement of surgeons and OR staff at the surgical field.

11. I disagree with Dr. Jarvis' opinion that he "rules in" the Bair Hugger as a possible source of Ms. Trombley's infection. Dr. Jarvis cites theoretical data showing differences in airflow in the OR with and without a Bair Hugger unit (Stocks et al, Legg et al, Legg and Hamer). However, these studies were not performed during actual surgical procedures with all of the attendant equipment and personnel. Furthermore, these studies did not demonstrate clinical outcomes because they did not show bacteria entering a patient's wound during surgery, did not show actual bacteria above the surgical field, and did not conclude a causal relationship between Bair Hugger and infections. These studies on which Dr. Jarvis relies expressly state they do not address causation. Contrary to Dr. Jarvis' opinions and conclusions, Moretti, et al, analyzed air samples taken over the surgical field during actual joint replacement cases with a Bair Hugger in use. I find this quote from his paper to be persuasive: **"Statistical analysis of the results demonstrated that the Bair Hugger system does not pose a real risk for nosocomial infections, whereas it does offer the advantage of preventing the potentially very severe consequences of hypothermia during major orthopaedic surgery."**

12. Dr. Jarvis cites two papers by Albrecht et al as evidence that the filtration unit of the Bair Hugger allows bacteria to pass through to the hot air flow in the blanket. I do not consider this relevant to the function of the Bair Hugger, as the air flow in the blanket is being applied to non-sterile skin – skin itself with a high bacterial load – far removed from the surgical site and separated by several layers of surgical drapes.

13. I do not agree with the evidence cited by Dr. Jarvis from the study by McGovern, et al. These authors first attempted to show changes in air flow associated with the Bair Hugger in a 'simulated' surgery. The soap bubbles used do not reflect the size or consistency of actual bacterial particles, and there is no way of knowing if the simulated OR and surgical set-up was in anyway comparable to the actual OR used for Ms. Trombley. Secondly, the unblinded before-and-after data presented as evidence for a decrease in infection rate with the conductive fabric blanket is considered very weak scientific evidence; multiple other interventions could have accounted for the change in results over time, including actions of the clinicians who knew that a change in devices had occurred. Causation can never be established by purely observational trials, and I strongly disagree with Dr. Jarvis emphasizing this paper over the other evidence in the literature.

14. Furthermore, a 2018 international statement on orthopedic infections summarized the consensus opinions of a large panel of experts, supported by more than 150 references. As noted by Dr. Jarvis, the experts agreed that forced air warming has the *potential* to disrupt air flow in the OR. However, Dr. Jarvis did not include the top line, and more relevant finding

of the panel: They addressed the question "Does the use of forced air warming during orthopedic procedures increase the risk of SSIs?" The answer from the experts was **"There is no evidence to definitively link forced air warming to an increased risk of SSIs/PJIs."** An overwhelming 93% of the experts supported this statement. The HVAC system itself is forced air. What Dr. Jarvis does not explain is how a *potential* to disrupt air flow makes a gigantic leap to a Bair Hugger actually causing an infection.

15. The consensus expert opinion that there is no evidence to link forced air warming systems to an increase in infections was reinforced by a 2017 letter from the FDA to all health care practitioners stating, in part "After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection." The FDA took the unusual step of sending this letter due to concern that clinicians would stop trying to keep patients warm, thus losing the known benefits of "less bleeding, faster recovery time and reduced risk of infections."

16. In my expert opinion, the Bair Hugger should not be "ruled in" as a possible source of bacteria in Ms. Trombley's case. Not only is there no evidence in the medical literature that the Bair Hugger causes or increases the risk of a deep joint infection, there is no evidence in Ms. Trombley's case that the Bair Hugger used during her surgery caused her infection. In fact, her treating orthopedic surgeon testified in his deposition that her infection probably developed post surgery based on his visual inspection of her wound during his revision surgery. Also, there is no evidence of the air quality in the operating room at the time of her surgery to suggest that Group B strep was circulating in the air at the time of her surgery.

17. Dr. Jarvis noted the risk of nosocomial infection posed by water-filled heater-cooler units in the OR. These devices contribute to different kinds of infections than suffered by Ms. Trombley, and moreover no such device was used in her care.

Conclusion

Ms. Trombley received excellent anesthesia and surgical care, with appropriate attention to prevention of perioperative infection during the procedure. Despite this she developed an infection many weeks after surgery. More likely than not this was the result of colonization of the surgical site with Group B Strep from her own gut or genitourinary system, abetted by her risk factors of hypertension, diabetes, obesity and chronic steroid use. Attempting to attribute this infection to a single piece of equipment used during the surgical procedure is a reach, especially considering the opinions of the most recent scientific literature and expert consensus that forced air warming does not increase the risk for SSIs. In my expert opinion it is far more likely that the Bair Hugger decreased her risk of infection by keeping her warm during the surgery.

I reserve the right to supplement this report and my expert opinions in the event new information is provided, and reserve the right to respond to and rebut new expert opinions offered by Plaintiff's experts that are not contained in the existing expert reports and are offered at their depositions or at trial.

Prior Testimony

I served as an expert consultant in approximately 20 medical malpractice cases from 1995-2010. I provided deposition testimony in 10 cases and testified in court in 3. I have not testified in any case in the past 8 years, including the 6 years I was the national Chief Quality Officer for the American Society of Anesthesiologists.

Fees

My fee for professional review of medical records and expert consultation is $500 per hour. My fee for testimony is $2500 per day, plus expenses.

Respectfully,

Richard P. Dutton, MD MBA

Richard Dutton, M.D.
Chief Quality Officer
US Anesthesia Partners